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PRACTITIONER'S REPORT

Assessors' attitudes toward and experiences of national quality standards: a qualitative study in Iran

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Abstract To establish a national accreditation system for medical laboratories, Iran has set national standards based on the international standard ISO 15189. Central to the accreditation process are the technical assessors. Their attitude in this regard and their experiences should be identified. This study aims to explore assessors' attitudes toward national laboratory accreditation and their experiences of assessment process in order to identify current gaps and suggest required interventions to solve them. A qualitative study using an open-ended questionnaire was employed. A total of 150 assessors working in the General Directorate of Laboratory Affairs participated in the study. While almost all Iranian laboratory accreditation assessors were generally supportive about the necessity of laboratory accreditation and cited benefits of this process, they pointed to improvement areas including developing assessor selection and appraisal criteria, continuous training, taking into consideration the heterogeneity of laboratories throughout the country, participation of professional associations and adopting measures to increase laboratories' involvement.

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Introduction

Medical laboratory services play a vital role in the healthcare system because decisions on diagnosis, treatment, and prognosis are often based on the results of medical laboratory examinations [1]. The quality of laboratory services, therefore, may greatly affect the quality and affordability of patient care, and any defects or errors impact on the care of each patient as well as the costs incurred by the healthcare system [2, 3]. Laboratory accreditation is recognized as an efficient tool to put in place quality management systems for achieving continuous improvement in laboratory services in a sustainable manner [4, 5].

While accreditation is becoming increasingly accepted around the world as a means of identifying technically competent laboratories [6], few developing countries have established their own national laboratory accreditation system. First nationally recognized laboratory standards should be developed [7]. In Iran, the Reference Health Laboratory (RHL) of the Ministry of Health (MoH) developed the national standards using ISO 15189 as a basis through a collaborative, consultative and consensus building process. The national standards came into operation in September 2007 and constitute minimum mandatory quality requirements for all medical laboratories throughout the country in private and public sectors [8, 9]. There are 52 medical science universities which supervise delivery of all health services in their catchment areas. At each university, the General Directorate of Laboratory Affairs (GDLA) is responsible for licensing and

supervising the laboratories [8, 10]. They assess the function of medical laboratories using their assessors [hereafter, assessor refers to both lead and technical assessors]. According to the literature, the continuous added value of accreditation is dependent upon qualified assessors [11] and the role of assessors as both auditors and mentors to facilitate continuing quality improvement is increasingly recognized [12, 13]. To improve the competence of GDLA assessors, RHL of MoH has held more than 20 educational workshops, since the beginning of the accreditation process. The assessors were also led to participate in benchmarking program to gain experience through auditing laboratories in other medical science universities.

Because of the important role of technical assessors, exploring their attitudes toward and experiences of laboratory accreditation is essential to provide greater insight into the process. The research studies about this issue are sparse, and more academic attention is required. The purpose of this study, therefore, was to contribute to a deeper understanding of the assessment process of laboratory accreditation from assessors' point of view. It helps to identify current gaps and deal with them to improve the quality of services.

Methods

To meet the objective of the study, a qualitative study was employed. One hundred and fifty national assessors were selected using the RHL database. The qualitative data were gathered using a questionnaire with 21 open-ended questions. The questions addressed different aspects of laboratory accreditation, and the assessment process derived from review of the literature and National documents [14]. Prior to distribution of the questionnaire, a pilot study was carried out and minor changes were made to finalize the questionnaire. The questionnaire had two main parts. The first part included assessors' socio-demographic information comprising educational level, field of study, length of relevant work experience and length of time the respondents had been working as assessor. The second part focuses on the assessors' perspective and experiences about laboratory accreditation and assessment process including their attitudes toward national accreditation scheme and related standards, assessment process and its mechanisms, professional requirements, and related challenges they are facing and solutions they suggest. Because the questionnaire contained some personal questions, approval was asked and obtained from the local ethics committee.

The qualitative data were analyzed using thematic analysis. The data were coded, and then themes were developed in order to generate new interpretive constructs and explanations. To reduce the bias, the data were coded independently by two coders (H.R. and N.A.) and disagreements have been resolved by research team. Afterward, using member check strategy, a draft report was provided to selected participants to collect their comments in order to ensure whether the findings were congruent with their perceptions and opinions.

Results and discussion

The assessors working in GDLA completed the questionnaire. They had an average job-related experience of 15 years (range 9–21) and had worked as assessors during 4 years (range 2–6). Most respondents (80 %) were medical laboratory scientists, followed by specialists in different laboratory fields. After analyzing the data, the themes were explored including assessors' attitudes toward laboratory accreditation, assessment process, professional requirements and selection criteria and challenges and proposed solutions.

Assessors' attitudes toward laboratory accreditation

The assessors seem to be highly supportive of the national mandatory accreditation and have a keen interest in their purposeful work of assessment leading toward the improvement of the quality of laboratory services. Other studies results concerning health professionals' attitudes toward accreditation demonstrate similar findings [15, 16].

In addition, many assessors pointed to significant benefits to healthcare system including commitment to best practice, quality assurance, harmonization of quality improvement in medical laboratories, possibility of better monitoring and evaluation. They believed that accreditation could ensure reliability of the laboratory services and enhance their credibility and increase competitiveness among laboratories. Moreover, better approaching to international standards, reduction of repeat laboratory testing, errors detection and prevention, staff and patient safety improvement were other benefits highlighted by assessors. Laboratory quality improvement as a factor affecting errors reduction is consistent with the results of a study by Plebani on detection and prevention of errors in laboratory medicine [3]. Some affirmed that accreditation can reduce waste of resources and their incurred costs on the healthcare system, in general, and patients in particular.

Conversely, a few number of participants stated that this process is time-consuming, bureaucratic and costly and has increased workloads, particularly paperwork, and stress for laboratory staffs. These findings are consistent with those of Gough and Reynolds [17].

Assessment process

The assessors examine the compliance of medical laboratories to national standards, and this process consists of on-site survey and follow-up actions for improvements conducted periodically [biannually] and for cause. Many assessors affirmed the vital role of assessment process as an effective tool for measuring quality requirements, while pointing to the consultative role of assessors.

In this regard, approximately all respondents pointed to the fundamental differences in domestic situation of different areas and emphasized this diversity should be taken into account, while assessing the progress of the laboratory standardization process. The heterogeneity of laboratories was also expressed in the results of two studies carried out in Thailand and Iran regarding laboratory accreditation [8, 18].

Moreover, some explained that differences, both structural and procedural, between hospital and outpatient laboratories should be considered. They believed that the management of hospital laboratory is more complex and their managers are dependent of the hospital management system as well. Pre-analytical errors may happen more often in hospitals due to its multidisciplinary nature. In addition, different shifts of work, diversity in laboratory tests and emergency laboratory tests in hospital laboratories are other differences. Plebani in his study regarding harmonization of quality indicators in laboratory medicine also cited pre- and post-analytical errors involving some breakdown in laboratories [19].

In addition, differences in assessing public and private laboratories due to different managerial structure, financing resources and complying with standards have been noted. This is consistent with another study carried out by Anjarani [9]. Most assessors also cited differences in assessing public and private laboratories due to differences in management, financing and complying with standards. They stated that the license of private laboratories is strictly renewed based on the accreditation results; however, such a process is not completely followed for public laboratories which may affect the standardization and the assessment process of public laboratories.

Some cited the important role of RHL and GDLA in the development and revising standards and related guidelines also training the assessors to facilitate the assessment process. Some believed that professional associations should be more involved and help RHL in the accreditation process including composition of standards and guidelines, setting criteria for assessor selection, evaluation of assessment process and training.

Professional requirements and selection criteria

All assessors in Iran's medical laboratory accreditation system are salaried and employed by GDLA. Given the critical role of assessors for ensuring the credibility and validity of the accreditation process [13], participants asserted that criteria for selection, training and appraisal of assessors should be clearly defined. Interest, motivation and commitment have been considered as fundamental factors for being an assessor. These findings are highly consistent with those of other studies [11, 13, 20].

The selection criteria, as perceived by the assessors, should include personal attributes, professional knowledge and experience. Most of the assessors included patience, justice, open mindedness, tenacity and observance as most important personal attributes which affect assessor performance, and interactions with accreditation body, other assessors and laboratory professionals. The participants stressed that a good assessor should have adequate and up-to-date knowledge. Therefore, they believed that initial and ongoing training focusing on quality concepts, national quality standards requirements and interpreting the standards, and techniques of compliance assessment should be hold in regular basis. Few assessors believed that successful completion of training should be considered as a requirement for assessor selection. In addition, participants believed that selection criteria should include levels of professional experiences such as having assessment expertise and experience, technical experience in laboratory as well as managerial skills. Some emphasized time management and meeting leadership skills as the most useful skills in this case. Studies in the European Union also demonstrate similar findings regarding assessor requirements [11, 20].

Although almost all assessors expressed that they were qualified according to proposed qualifications criteria, fewer than half reported being completely satisfied with their performance. They pointed out that qualification and competence of assessors should be assessed by both accreditation body and laboratory professionals based on their performance. In this regard, some cited that the accreditation body should have data regarding the assessors' requirements including training, competence and their performance in actual assessment.

Challenges

Various challenges in implementing laboratory standards were addressed by the assessors. The most significant challenges were lack of motivation of laboratory professionals, shortages in both financial and human resources. Lack of motivation among laboratory professionals, perceived by assessors, resulted in few laboratories' being involved in standardization. Some believed that laboratory professionals were not adequately informed about the quality standards and their necessity and benefits. These findings are in consistence with the results of a study by

Pongpirul et al. [21] in Thailand. Some participants pointed out that lack of motivation in the laboratory staffs was due to lack of support from laboratory senior management and weak quality culture. Lack of compulsory licensing, particularly among public laboratories seems another cause of lack of motivation among laboratories professionals.

Many of the respondents believed that problems with financial and human resources in the laboratories had been mainly due to low laboratory tariff levels in Iran. A number of assessors also cited that implementing standard requirements may impose concerns about high expenditure; particularly, those were in small cities. The issue of cost as a barrier to standardization among laboratories is in consistence with findings of a study by McGrowder et al. [6] in Jamaica.

With regard to the challenges of the assessment process, lack of assessor was an important challenge identified. A large majority of the assessors believed that more assessors are needed to increase both frequency of assessment and the hours spent by the assessors in the laboratories. Lack of incentives [financial and non-financial] for the assessors and inadequate policy-level support for accreditation also perceived as important factors affecting the assessors' dissatisfaction. Some pointed out that they had difficulties in the standards interpretation and they considered inadequate training as the cause of this problem. Similarly, McGrowder et al. [6] highlighted challenges with interpretation of the standards in their study in Jamaica. A small minority of assessors believed that the standards also should be more realistic and pay more attention to local needs. They also cited diversity of laboratories in public and private sectors, and different levels of quality and performance. They emphasized that the diversity has not been taken into account in the accreditation process.

Proposed solutions

While there are concerns about challenges faced by the laboratory accreditation, some solutions have been proposed for current problems and improvement, including building quality culture to encourage quality standards implementation, personnel involvement and motivation, paying high attention to laboratory personnel training, development of better interactions between assessors and laboratory professionals and improving legal issues concerning licensing particularly for public laboratories. The issue of mandating laboratories to be licensed is in consistence with the findings of other studies in Ghana and Jordon [22, 23].

Moreover, cost issues have been perceived as a barrier and participants suggest that reasonable increasing of laboratory tariff levels may help laboratories to overcome financial and human resources problems. Providing financial rewards and professional recognition for laboratories complying with the standards were also cited by some assessors as a motivation factor. The issue of rewarding progress has been also discussed in a study on improving the quality of laboratory systems in the African Region [7].

About challenges in relation to assessment issues, many assessors affirmed the necessity of recruiting more staff and volunteers as assessors. Some also pointed to some practices to improve the assessment process including, providing financial rewards and professional recognition for assessors, developing assessor selection, recruitment and retention criteria with participation of the professional associations and adjoining the principles of quality management system to academic curriculum of laboratory sciences. Moreover, some considered creating initial and ongoing training mechanisms as critical efforts to ensure sound understanding of the standards and assessment techniques by the assessors. The necessity of policy-level support for laboratory accreditation has been suggested which is consistent with the findings of studies carried out in Serbia and Thailand [18, 24].

While many assessors expressed a need for harmonization among laboratories, they pointed to the necessity of revising the standards and related guidelines with involvement and participation of the professional associations. In this regard, many assessors believed that due to wide heterogeneity in the laboratories, application of the same approach for implementing the standards in all laboratories throughout the country would be difficult. Adopting a staged approach for implementation might be useful. Moreover, recognizing different levels of quality improvement among the laboratories and formulating different operational plans according to laboratories' resources may facilitate the pace of improvement. In this regard, other studies in Iran, Pakistan and Thailand demonstrate similar findings [10, 18, 25, 26].

Conclusion

Exploring assessors' attitudes toward national laboratory accreditation and their experiences of assessment process is a useful step to identify current gaps and suggests required interventions to solve them. In sum, while the Iranian assessors generally agree on necessity and progress of laboratory accreditation, they stress that relevant authorities should put in place purposeful measures and approaches required to strengthen integrated national laboratory accreditation system in order to ensure the provision of accurate, reliable and timely laboratory tests results.

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